

**PATENT/Docket No. PC9455A**

Appl. No. 09/508,892

Filing Date: March 17, 2000

Amdt. dated July 15, 2004

Reply to Office action of April 19, 2004

### **REMARKS/ARGUMENTS**

Applicants respectfully request entry and consideration of the foregoing amendments.

#### **I. Amendment to the Claims**

The claims are amended as noted above. Claim 34 is canceled as co-extensive with claim 25. Support for new claim 37 can be found in claim 25 prior to the instant amendment. The remaining amendments merely renumber the claims, and provide proper antecedent basis, in compliance with the Examiner's comments in the Office action regarding the improper numbering of the claims. Thus, claims 25-33, and 35-37 are pending, as amended above. The amendments do not constitute new matter.

#### **II. Alleged Independent Invention, Constructive Election, and Withdrawal of Claims**

The Office action states that the invention is "now...directed to (a) a stable implant when (b) exposed to electron irradiation" and that the invention as now claimed is patentably distinct from the previously claimed invention. Further, it is alleged that the original invention was to actives of low solubility, and that now the claims are directed to actives with antioxidants. The Office continues to allege that "claims 25-29 are withdrawn from consideration as being directed to a non-elected invention." Applicants traverse this restriction.

According to the MPEP, a restriction requirement is proper when (A) the inventions are independent or distinct and (B) there is a serious burden on the Examiner in searching the entirety of the claimed invention. MPEP § 803.

Applicants respectfully point out that the originally-filed claims provide support for the entirety of the pending claims. For example, claim 10 as pending after the preliminary amendment recited "[a]n implant as claimed [in] claim 1 which contains an antioxidant or a reducing agent." Claim 12 as pending after the preliminary amendment recited "[a]n implant as claimed in claim 1 which is suitable for sterilization, or has been sterilized, by irradiation." (See, Preliminary Amendment to PCT/EP98/05720, filed March 17, 2000). The Office has issued three (3) substantive Office actions on the merits of the pending claims, yet it has not issued a restriction requirement during the course of prosecution. Thus, as the merits of the claimed invention have been examined three times, there can be no serious burden placed on the Examiner in searching the entirety of the claimed invention.

Accordingly, Applicants respectfully request reconsideration of the decision to withdrawal claims 25-29 from consideration as non-elected, and that all the pending claims be examined together.

#### **III. Rejection of Claims under 35 U.S.C. § 112, 1<sup>st</sup> paragraph**

Claims 25-36 stand rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, for allegedly failing the written description requirement. Specifically, it is alleged that the specification fails to describe implants that are stable for up to 30 weeks at 30°C at an electron irradiation level of up to 25 kGy, in such a way that one of skill in the art would have notice that Applicants possessed the invention.

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Above, Applicants have cited to support for the pending claims. In particular, support for the recited stability conditions that are alleged to be at issue in this rejection can be found in the specification, for example, at page 9, line 20 – page 10, line 6, and Figure 2. Thus, the claims are fully described by the specification in such a way that one of skill would have notice that Applicants possessed the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, 1<sup>st</sup> paragraph.

#### **IV. Rejection of Claims under 35 U.S.C. § 102(b)**

Claims 30-32 stand rejected under 35 U.S.C. § 102(b), alleged to be anticipated by Roorda et al. (US Patent 5,543,156) in view of Miller (US Patent 5,728,719). Specifically, the compositions of the Roorda-Miller combination are alleged to comprise the same components as those recited in the claimed invention, and thus, meet the stability and irradiation requirements of the claimed invention. Applicants respectfully disagree with this assertion.

According to MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)."

Applicants respectfully maintain that this basis of rejection is neither proper nor of record (as asserted in the Office action at page 3). From the language of the Office action, it is seems that both the Roorda and Miller references are relied on to provide essential elements of the claim, and are thus used in combination. Such a combination of two or more references is an improper basis for rejections under 35 U.S.C. § 102(b). According to the M.P.E.P., "a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to: (A) Prove the primary reference contains an 'enabled disclosure;' (B) Explain the meaning of a term used in the primary reference; or (C) Show that a characteristic not disclosed in the reference is inherent." (M.P.E.P. § 2131.01). Neither the disclosure of Roorda nor the disclosure of Miller is alleged to provide any of the above three requirements. Applicants request clarification of the basis for the rejection under 35 U.S.C. § 102(b); however, Applicants maintain that these references fail to properly anticipate, or render obvious, the claimed invention as reasoned below.

Even assuming that the above rejection is intended to be alleged under 35 U.S.C. § 103(a), and not § 102(b), the combination of Roorda and Miller still fail to anticipate or render the claimed invention obvious, when taken alone or in combination. Roorda teaches erodible delivery devices that comprise (a) a body formed of a bioerodible polymer or polymers together with a required excipient, and (b) an active agent. The delivery devices of Roorda are disclosed as providing increased control over and improved reproducibility of the release profile of active agent from the polymer. Roorda does not disclose, teach, or suggest a solid implant comprising at least one parasitocidal compound having an aqueous solubility below 100 µg/ml, and at least one antioxidant, wherein said solid implant is stable at 30°C when exposed to electron irradiation.

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The disclosure of Miller fails to cure the deficiency of Roorda. Miller teaches compositions comprising ovidically-active amounts of nitrogen-containing heterocyclic compounds for the control of ectoparasites and endoparasites. These compositions can be in the form of sustained release implants, such as are known in the art (Col. 7, ln. 6-27). Miller fails to teach a solid implant comprising at least one parasitocidal compound having an aqueous solubility below 100 µg/ml, and at least one antioxidant, wherein said solid implant is stable at 30°C when exposed to electron irradiation. The only disclosure Miller provides regarding antioxidants are with regard to animal feed formulations (Col. 7, ln. 60 – Col. 8, ln.5). Miller's Example 9, entitled "Monolithic 150 mg Implant" does not comprise an antioxidant. Thus, nothing in the disclosure of Miller would teach, suggest, or motivate one of skill in the art to combine at least one antioxidant and at least one parasitocidal compound having an aqueous solubility below 100 µg/ml, to form a solid implant as claimed. Therefore the disclosures of Roorda and Miller, taken alone or in combination, do not render the claimed invention unpatentable under either 35 U.S.C. §§ 102(b) or 103(a).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the above rejection under 35 U.S.C. § 102(b).

**V. Rejection of Claims under 35 U.S.C. § 102(e)**

Claims 30-32 stand rejected under 35 U.S.C. § 102(e), alleged to be anticipated by the disclosure of Miller (US Patent 5,728,719). Specifically, Miller is essentially re-alleged as stated above as providing solid implants of Doramectin, BHA, BMT, and are sterilizable.

Applicants respectfully disagree with this assertion, for the reasons stated above in Section IV. Applicants reassert the arguments as stated above, and thus, the disclosure of Miller, fails to anticipate the claimed invention under 35 U.S.C. § 102(e).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the above rejection under 35 U.S.C. § 102(e).

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**Conclusion**

In light of the above argument and the accompanying Request for Continued Examination under 37 C.F.R. § 1.114, Applicants request that prosecution of the application be reopened. Further, in light of the argument, Applicants believe that the application is in condition for allowance and earnestly solicit a favorable determination.

Respectfully submitted,



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